



<382> Elastomeric Component Functional Suitability in Parenteral Product Packaging/Delivery Systems

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Expert Committee	Packaging and Distribution Expert Committee

In accordance with the Rules and Procedures of the Council of Experts, this is to provide notice that the General Chapters—Packaging and Distribution Expert Committee intends to revise <382> Elastomeric Component Functional Suitability in Parenteral Product Packaging/Delivery Systems.

Comments were received indicating that a revision is needed to the *Needle Self-Sealing Capacity* test requirement to penetrate elastomeric closures 1.5 times. It was noted that this differs from ISO 11608-3, which specifies only 1.0 penetrations. Applying the *USP* requirement could result in excessive punctures—up to 252 for one cartridge product—which may lead to leak test failures, even though such usage does not reflect typical patient behavior.

To resolve this, USP will revise the requirement to specify 1.0 penetrations as the maximum number of scheduled punctures.

It is anticipated that the revision will be posted as a Revision Bulletin.

Should you have any questions, please contact Desmond G. Hunt, Senior Principal Scientist, Scientific Liaison to the General Chapters—Packaging and Distribution Expert Committee (301-816-8341 or dgh@usp.org).